REMARKS

The Examiner provides a single rejection in that Claims 1-12 are allegedly rejected under 35 U.S.C. § 103(a) as being unpatentable over Dorman et al., Toyosawa et al. or Coombes et al. The Applicants interpret the Examiner's phrasing of the three cited references to indicate that the Examiner intends a combination. The Examiner has provided no other factual information to provide a basis for rejecting the claims other than the three cited references. Unless one makes the "factual inquiries" demanded by *Graham v. John Deere*, 383 U.S. 1 (1966) one is only paying "lip service" to it. *In re Dailey,* 53 CCPA 1029, 157 F.2d 669, 149 USPQ (BNA) 47 (CCPA 1966)(J. Smith dissenting) Therefore, the Applicants rebut the Examiner's assertion that Claims 1-12 are unpatentable over Dorman et al., in view of Toyosawa et al., or in further view of Coombes et al. on the basis that the Examiner has failed to establish a *prima facie* case of obviousness.

I. The Claims Are Not Obvious

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A *Prima Facie* Case Of Obviousness. The Examiner is reminded that if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. In the present Office Action, the Applicants clearly demonstrate that the Examiner's rejection does not meet these criterion.

Specifically, the Examiner asserts Dorman et al. as a primary reference provides the teachings of Toyosawa et al. and Coombes et al. as secondary references in an attempt to compensate for Dorman's deficiencies. The Applicants disagree and argue that the Examiner is improperly "picking and choosing" elements from references without any proper motivation to combine the references, and even if the references were properly combined they do not teach a composition having a controlled porosity.

A. The Examiner Is "Picking And Choosing" References

The Examiner justifies that the combination of references support a 35 U.S.C. § 103(a) rejection by stating:

> Patentees disclose the claimed composition comprising a polymer of the claimed type such as a polylactic acid, an inorganic compound of the claimed type such as hydroxyapatite, calcium phosphate or glass powder and having a porosity of greater than 80%. Note col 7 first full par. and example 14 of Dorman et al: col 5 lines 17-35, col 6 line 19: and col. 7 lines 23-35 of Toyosawa et al.: and col 9 lines 17, 34-36 and example 8 of Coombes et al. *Office Action page 2 ¶ 3.*

The Applicants' argument below demonstrates that none of these references provide any motivation to combine one reference with any other of the references. Clearly, the Examiner is "picking and choosing" from each reference only ONE specific element on which to provide a motivation for combination instead of considering the reference as a whole. This approach is impermissible according to the Federal Circuit. *In re Hedges*, 228 USPQ 685, 687 (Fed. Cir. 1986) citing *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965)("It is impermissible, within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."). As such, the Applicants argue that the Examiner has provided an improper combination of references. On this basis alone, the Applicants respectfully request the Examiner withdraw the rejection.

Nonetheless, without acquiescing to the Examiners' argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended the claims to further define and clarify one preferred embodiment by reciting that the composition or matrix may has a "controlled porosity". This element is fully explained in the Applicants' specification Section IIB, spanning pages 10 to 16.

B. There Is No Combined Teaching Of A Controlled Porosity

1. Dorman et al. Fails To Teach Success

As a primary reference Dorman et al. should (but does not) provide the most persuasive evidence supporting the alleged obviousness rejection. The Applicants assert that Dorman et al. lacks any mention or suggestion to create a composition having a "controlled porosity" to modify its teachings create the preferred embodiment of the Applicants.

Dorman et al. teaches a porous composition only following exposure of a preexisting composition to a pore-forming agent. Importantly, Dorman et al. teach a **non-porous** composite material when mixing a polymer and a inorganic compound as disclosed in Examples 8, 9 and 10. The presence of porosity, requires, as taught in Example 11, the addition of either poly(2-ethyl-2-oxazoline) or sodium chloride.;

> Porositization of the composite materials described herein may be attained by intimately blending the powdered composite with a compatible, **pore-forming agent**. ... includ[ing] water-soluble polymers ... and/or water soluble inert materials. *Dorman et al.*, col 7 ln 3-11 [emphasis added].

It is clear, however, that the resultant porosity is not controlled. Dorman et al. discloses no compositions having predictable variations in porosity. Indeed, Dorman et al. only uses the term "porosity" in a general sense and does not provide any quantitative information as to a relative percentage ratio obtained by calculating the pore size volume to total composition volume. Furthermore, Example 14 demonstrates that the teachings of Dorman et al. is limited to a post-synthesis microscopic identification of a resultant pore size and not a pre-synthesis prediction of the pore volume:composition total volume ratio;

> Microscopy of a section of the porositized product showed pore sizes of 10-25 microns. *Dorman et al.* col 10 ln 53-54.

and

> Microscopy of a section of the disc showed varied pore sizes, some in excess of 100 microns. *Dorman et al.* col 10 ln 63-64.

The teachings of Dorman et al., therefore DO NOT **provide any suggestion** to one skilled in the art that a porous composition having controlled porosity is either preferable, possible **or has any reasonable expectation of success**.

2. Toyosawa et al. Is Not Enabling

The Examiner cites Toyosawa et al. at col 5 ln 17-35, col 6 ln 19 and col 7 ln 23-35 as a secondary reference that allegedly fills Dorman's deficiencies by disclosure of a composition having a porosity greater than 80%, glass powder and polystyrene. *Office Action pg 2 ¶ 3.* The Applicants disagree.

The Applicants argue that Toyosawa et al. does not fill Dorman's deficiency in teaching a composition having a controlled porosity. For example, the Examiner points to Toyosawa's sole and singular support in a futile attempt to teach porosity;

> The porosity is desirably at least 40%, especially 50 to 95%. *Toyosawa et al.* col 5 ln 27.

The Examiner is reminded that a proper 35 U.S.C § 103(a) reference must be enabling. In order to render a claimed apparatus or method obvious under Section 103, the prior art must enable one skilled in the art to make and use the apparatus or method. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989); and *Application of Payne*, 606 F.2d 303, 314 (CCPA 1979). Toyosawa et al. merely contemplates a desire for porosity ranging between 40-95%. The Applicants point out that Toyosawa et al. does not describe compositions having porosities that are predicted prior to synthesis.

Moreover, Toyosawa et al. does not define any compositions in terms of porosity, only in strand and cell diameters, for example;

> The strands 1 have an average diameter d of up to 10 μm, preferably 1 to 7 μm and the cells 2 have an average diameter D of up to 80 μm, preferably 2 to 50 μm. *Toyosawa et al.*, col 7, ln 43-45.

The Applicants conclude, therefore, that Toyosawa et al. is silent on any ability or suggestion to control the porosity of a composition.

3. Coombes et al. Fails To Teach Porosity

The Examiner cites Coombes et al. at col 9 ln 17, 34-36 and Example 8 as a secondary reference that allegedly fills deficiencies left by Dorman et al. by the disclosure of a composition having calcium metaphosphate, microporosity, and tricalcium phosphate. *Office Action* ¶ *3.* The Applicants disagree.

The Applicants argue that Coombes et al. does not fill Dorman's deficiency in teaching a composition having a controlled porosity. Coombes et al teaches a composition that is created by treating a preformed gel with a dehydrating agent to induce microporosity;

> An acetone-based gel of TCP-filled, L-PLA, produced as described above, was immersed in methanol on demold for five days, then air dried for four days. The microporous material obtained exhibited a shrinkage of 26% and a density of 0.27 g/cm^3. *Coombes et al.*, Example 8, col 13 ln 35-39.

Gel shrinkage disclosed by Coombes et al. occuring during the conversion into a microporous material is a function of the drying process:

> ... the extent of shrinkage and, therefore density of microporous materials ... can be controlled by partially drying the gel ... to a desired level and extracting/replacing the solvent or nonsolvent with water ... *Coombes et al.*, col 9 ln 54-59.

These alterations in density are not equivalent with the Applicants' controlled porosity. Coombes et al. does not contemplate any specific values for composition porosity or suggest that controlling composition porosity is feasible or desirable. Specifically, porosity is a ratio of total pore volume to total composition volume (see, *Applicants' Specification*, pg 5 ln 9-11), whereas density is a ratio of total composition weight to total composition volume (*supra*).

The Applicants conclude, therefore, that Toyosawa et al. is silent on any ability or suggestion to control the porosity of a composition.

C. Conclusion

The Applicants respectfully request that the Examiner remove the obviousness rejection because the three cited references represent an improper combination, and even if they were a proper combination, they fail to teach a composition having a controlled porosity. As a result, the Examiner has failed to establish a *prima facie* case of obviousness.

CONCLUSION

The Applicant believes that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect at 617.252.3353.

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Peter G. Carroll
Registration No. 32,837

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
415.904.6500

APPENDIX I
MARKED-UP VERSION OF REWRITTEN CLAIMS
PURSUANT TO 37 CFR § 1.121 (c)(1)(ii)

1. (Amended) A [solvent free solidified matrix] composition, comprising [a mixture of]:

   i) a solid matrix having a controlled porosity that is substantially free of solvent comprising a mixture of;

      a)[i)] at least one polymer, wherein said polymer is selected from the group consisting of poly(L-lactic acid), poly(D,L-lactic acid-co-glycolic acid (PLGA), poly(methyl methacrylate) and polystyrene; and

      b)[ii) at least one inorganic compound wherein said inorganic compound is selected from the group consisting of hydroxyapatite, calcium phosphate and glass powder[;

   wherein said matrix has a porosity of greater than approximately 80%].

2. (Amended) The [solvent free solidified matrix] composition of Claim 1, wherein said controlled porosity is greater than approximately 85%.

3. (Amended) The [solvent free solidified matrix] composition of Claim 1, wherein said controlled porosity is greater than approximately 90%.

4. (Amended) The [solvent free solidified matrix] composition of Claim 1, wherein said controlled porosity is greater than approximately 95%.

5. (Amended) The [solvent free solidified matrix] composition of Claim 1, further comprising a simulated body fluid contacting said matrix.

6. (Amended) A composition, comprising:

   a) a three dimensional structure formed by a solid matrix having a controlled porosity; and

b) a simulated body fluid contacting said structure, wherein said matrix comprises a mixture of;

i) at least one [inorganic] polymer, wherein said polymer is selected from the group consisting of poly(L-lactic acid), poly(D,L-lactic acid-co-glycolic acid (PLGA), poly(methyl methacrylate) and polystyrene; and

ii) at least one inorganic compound wherein said inorganic compound is selected from the group consisting of hydroxyapatite, calcium phosphate and glass powder[; wherein said matrix has a porosity of greater than approximately 80%].

9. (Amended) The composition of Claim 6, wherein said controlled porosity is greater than approximately 85%.

10. (Amended) The composition of Claim 6, wherein said controlled porosity is greater than approximately 90%.

11. (Amended) The composition of Claim 6, wherein said controlled porosity is greater than approximately 95%.